REMARKS

In a paper mailed from the Patent Office on March 23, 2004, the following statement is made concerning reference AR cited in Applicant's Supplemental Information Disclosure Statement filed on December 29, 2003.

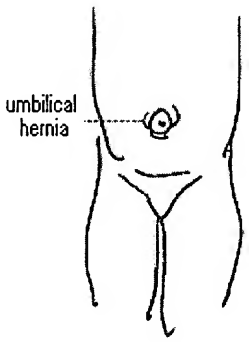
> The reference cited in the Information Disclosure Statement by the applicant reads on the present claims. However, the examiner requests help from the Applicant in determining the date of the rejection (sic) in order to make a proper rejection.

Since the device described in cited reference AR (which is not admitted to be prior art) is very different from that claimed by Applicants, we begin with a discussion of the features and use of the device disclosed in reference AR. The device will be alternatively referred to herein as the "Lohmann device".

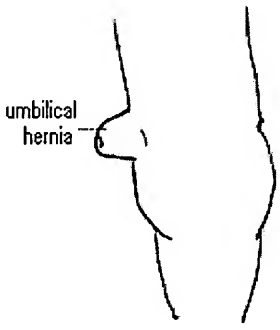
The Lohmann Device

The Lohmann device is described on the packaging as an "umbilical hernia plaster". An umbilical hernia occurs due to a weakness or a small hole in the abdominal wall at the umbilicus (belly button) and the severity is measured by the extent to which abdominal contents bulge through the weakness or hole in the abdominal wall and become visible as a bulge in the skin in the umbilicus area. This is shown in the front and side views below. Umbilical hernias can be most pronounced when a child strains or cries.

Front View



Side View



Treatment for umbilical hernia is observation. More than 95% of such abdominal wall openings will close by the time the child reaches 5 years of age, and more than 90% close by age 3. Large hernias (openings of greater than 1 inch) are sometimes closed surgically, but surgical intervention is not typically undertaken for smaller hernias due to the risk associated with general anesthesia. **In the past, various methods of compression such as banding, tape, strapping or application of plaster were employed. However, such techniques have not been shown to be effective and can cause infection and skin irritation.** To be clear, the abdominal wall opening referred to above is not an opening in the skin - an opening in the skin is not a feature of an umbilical hernia. Rather, a bulge in the skin appears as the contents of the abdomen are forced through an opening in the abdominal wall. Clearly the Lohmann device is not a wound closure device.

Applicant has reviewed the Lohmann website (http://www.lohmann-gruppe.de) but has been unable to locate any information about, or reference to, the umbilical hernia plaster described in Reference AR. Applicant is unaware of the date of the packaging/instruction sheet submitted as Reference AR. Additionally, Applicant has no specific knowledge as to whether the device was sold, or otherwise made publicly available. The device appears to have been intended to be used as a compression bandage to prevent abdominal contents from protruding through the hole in the abdominal wall which is the umbilical hernia

Applicant's Invention

First, Applicant points out that the claimed invention is a wound closure device intended for closing a wound (laceration or surgical incision) and aligning the edges of the closed wound with great precision. The Lohmann device is essentially compression strapping intended to be placed on intact skin which covers a hole in the abdominal wall to prevent abdominal contents from protruding through the hole and creating a bulge in the skin. As indicated previously, Applicant disagrees with the statement in the Office communication to which this paper is responsive, that:

> The reference cited in the Information Disclosure Statement by the applicant reads on the present claims.

Claims 1-20 are directed toward a two-component medical device and methods for using the device. All claims are limited to two-component medical devices of the type shown in Figs. 7 and 8 in which a single elongated connector (15 and 35) is associated with each component. Each of the elongated connectors extend in an offset manner from an edge of the first or second flat flexible components. Pulling elements extend from the elongated connectors and are adapted for lateral translation of the associated flat flexible component toward a wound edge.

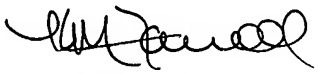
While the cited Lohmann device is a two-component device, one of the two components has the equivalent of a plurality of elongated connectors. Furthermore, as discussed above, there is no "wound edge" associated with an umbilical hernia. Thus, Applicant's claims 1-20 do not read on the cited Lohmann device.

Cancelled Claims 21-41 are directed toward a skin stretching embodiment which is disclosed in the subject application beginning at page 10, line 26, and continuing through page 11, line 19. In the interest of expediting prosecution, Claims 21-40 have been cancelled. Applicant reserves the right to prosecute these claims in a related application.

Summary

In light of the above amendments, consideration of the subject patent application is respectfully requested. Any deficiency or overpayment should be charged or credited to Deposit Account No. 500282.

Respectfully submitted,



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